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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,495	07/28/2000	David White	210147.0039/16U1	3801

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EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	15

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/628,495	David White
Examiner	**Group Art Unit**
Diana Johnson	1634

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- [X] Responsive to communication(s) filed on 5/7/02.
- [ ] This action is **FINAL.**
- [ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- [X] Claim(s) 1-41 is/are pending in the application.
  - Of the above claim(s)____ is/are withdrawn from consideration.
- [ ] Claim(s)____ is/are allowed.
- [ ] Claim(s)____ is/are rejected.
- [ ] Claim(s)____ is/are objected to.
- [X] Claim(s) 1-41 are subject to restriction or election requirement.

Application Papers

- [ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- [ ] The proposed drawing correction, filed on____ is [ ] approved [ ] disapproved.
- [ ] The drawing(s) filed on____ is/are objected to by the Examiner.
- [ ] The specification is objected to by the Examiner.
- [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- [ ] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).
  - [ ] All [ ] Some* [ ] None of the CERTIFIED copies of the priority documents have been
  - [ ] received.
  - [ ] received in Application No. (Series Code/Serial Number)____.
  - [ ] received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

- [ ] Information Disclosure Statement(s), PTO-1449, Paper No(s).____
- [ ] Interview Summary, PTO-413
- [ ] Notice of Reference(s) Cited, PTO-892
- [ ] Notice of Informal Patent Application, PTO-152
- [ ] Notice of Draftsperson's Patent Drawing Review, PTO-948
- [X] Other Detailed Action

Office Action Summary

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7-9, 13-16, and 39-41, drawn to methods of diagnosing and/or detecting predisposition for a bone-related disorder requiring determination of a nucleotide sequence, classified in class 536, subclass 25.32.

II. Claims 1-6, drawn to methods of diagnosing a bone-related disorder requiring detection of differences in gene expression levels, classified in class 435, subclass 6.

III. Claims 1-6, drawn to methods of diagnosing a bone-related disorder requiring determination of the protein content of a patient's tissue, classified in class 435, subclass 7.1.

IV. Claims 1-6, 10-12, 17-18, 21, and 23-24, drawn to methods of diagnosing and/or alleviating a bone-related disorder requiring administering to a patient an MRR protein binding agent or antagonist, classified in class 424, subclass 130.1.

V. Claims 17-19 and 23-24, drawn to methods of alleviating a bone-related disorder requiring administering an MRR protein, classified in class 514, subclass 2.

VI. Claims 17-20 and 23-24, drawn to methods of alleviating a bone-related disorder requiring administering a vector, classified in class 514, subclass 44 and class 435, subclass 320.1.

VII. Claims 17-18 and 23-24, drawn to methods of alleviating a bone-related disorder requiring administering an agonist of MRR protein activity, classified in class 514, subclass 2.

VIII. Claims 17-18 and 23-24, drawn to methods of alleviating a bone-related disorder requiring administering an enhancer of mrr expression, classified in class 514, subclass 2.

IX. Claims 17-18 and 22-24, drawn to methods of alleviating a bone-related disorder requiring administering an inhibitor of mrr expression, classified in class 514, subclass 44 and class 536, subclass 24.5.

X. Claims 25-31 and 37-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring determining MRR protein activity, classified in class 435, subclass 7.4.

XI. Claims 25-27, 29-33, and 37-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring comparing mrr gene expression, classified in class 435, subclass 6.

XII. Claims 25-27, 34, and 37-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring determining a bone phenotype, classified in class 435, subclass 7.24.

XIII. Claims 25-27, 35, and 37-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring administering the compound to a transgenic animal, classified in class 800, subclass 3.

XIV. Claims 25-28 and 36-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring determination of protein activity in an artificial membrane, classified in class 435, subclass 7.2.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I-XIV are patentably distinct methods. First, Inventions I-IV and V-IX, I-IV and X-XIV, and V-IX and XIV differ from each other in having different objectives: Inventions I-IV have the objective of diagnosing a bone-related disorder, Inventions V-IX have the objective of treatment, and Inventions X-XIV have the objective of determining the usefulness of a test compound. Furthermore, each of Inventions I-XIV requires the use of different combinations of reagents and the practice of differing method steps. Invention I requires the use of, e.g., sequencing reagents in a step of determining a nucleotide sequence. Invention II requires the use of, e.g., oligonucleotide probes in a step of determining gene expression levels. Invention III requires the use of, e.g., a labeled antibody in a step of determining the protein content of a tissue. Invention IV requires the use of, e.g., a binding reagent in a pharmaceutical carrier in a step of administering a binding reagent to a patient. Invention V requires the use of a portion of an MRR protein in a step of administering a polypeptide to a patient. Invention VI requires the use of an expression vector in a step of administering a vector to a patient. Invention VII requires the use of an agonist in a step of administering an agonist to a patient. Invention VIII requires the use of mrr expression enhancer in a step of administering an enhancer to a patient. Invention IX requires the use of, e.g., an

antisense oligonucleotide in a step of administering an mrr expression inhibitor. Invention X requires the use a cell comprising biologically active MRR in a step of comparing MRR activity. Invention XI requires a step of a test compound and , e.g., an oligonucleotide probe in a step of determining mrr gene expression. Invention XII requires the use of, e.g., a microscope in a step of determining a bone phenotype. Invention XIII requires the use of a non-human transgenic animal in a step of administering a compound to said animal. Invention XIV requires the use of artificial membranes in a step of determining activity in said membrane. Accordingly, the methods of Inventions I-XIV are patentably distinct from each other.

3. It is pointed out that applicants have presented several claims in improper Markush format (see *Ex parte Markush*, 1925 C.D. 126 and *In re Weber*, 198 USPQ 328). Method claims encompassing multiple distinct methods requiring the use of different reagents in distinct method steps are improperly joined, as the different methods encompassed by the claims differ to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, restriction has been set forth for each of the various groups, irrespective of the improper format of the claims. Claims 1-6, 17-19, 23-27, 29-31, and 37-38 have been included in multiple groups, and if elected, will be examined only as they read upon the invention of the elected group.

Upon election, applicants are further required to amend the claims to set forth the elected inventive group, otherwise the claims under examination will be rejected as being in improper Markush format.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-XIV require different searches that are not co-extensive, examination of these distinct Inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
June 30, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600